K090249
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APR - 3 2009

510(k) Summary

Submitter:	Harbinger Medical, Inc.
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	Eden Prairie, Minnesota 55344
Contact:	Harold Hoium
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Date Prepared:	January 30, 2009
Trade Name:	Micro-Induction 1000 system (MI-1000 System)
Classification Name	21 CFR 870.2340 (Electrocardiograph) and
And Regulation Number	21CFR 870.2360 (Electrode Electrocardiography)
Class:	Class II
Product Code:	DPS and DPX
Predicate Devices:	Micro-Induction 1000 System (MI-1000) (K013615)
Device Description:	The device consists of an IBM compatible PC, nine skin surface electrodes, one electronics board, a patient interface module and software. Seven of the electrodes are used for sensing cardiac electrical activity. The remaining two electrodes are used to apply low level current pulses (maximum 40 milliamps) to the patient. This technology uses noninvasive, externally applied, subthreshold (low amplitude) far-field stimulus while acquiring electrocardiogram data.
	The MI-1000 system is a tool used to identify heart cells that are significantly less stable than normal or conduct

	slower than normal and, thus, are an indication of cardiac electrical problems.
Intended Use:	The MI-1000 system is used to measure Wavelet Surface Residuum indices at rest and during low level electrical stimulation during the cardiac refractory period. This data is presented in a graphical format for interpretation by a trained physician. The MI-1000 system is also used for the measurement of SAECG indices. The MI-1000 system should be used only as an adjunct to clinical history and the results of other noninvasive and /or invasive tests.
Technological Characteristics:	The modified MI-1000 system is substantially equivalent to the original MI-1000 system and utilizes all of the same fundamental technology to capture the ECG signal from the patient. The only change for the current model is in the signal post-processing and display. All of the displayed information is subject to physician interpretation.
Performance Data-non-clinical:	A complete software validation and verification was completed to verify that the acquired data was able to be correctly analyzed and the Wedensky indices were correctly calculated and displayed. All testing successfully met the required criteria.
Performance Data - clinical:	No clinical testing was required.
Conclusion:	The modified Micro-Induction 1000 system is substantially equivalent to the previously cleared version of the Micro-Induction 1000 system.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Harbinger Medical, Inc.
C/O Harold Hoium
10125 Crosstown Circle, Suite 105
Eden Prairie, Minnesota 55344

Re: K090249
Trade/Device Name: Micro-Induction 1000 System
Regulation Number: 21 CFR 870.2340 (Electrocardiograph)
Regulatory Class: Class II
Product Code: DPS and DPX
Dated: March 18, 2009
Received: March 20, 2009

Dear Mr. Hoium:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K090249

Device Name: Micro-Induction (MI) 1000 System

Indications For Use:

The MI-1000 is used to measure Wavelet Surface Residuum indices at rest and during low level electrical stimulation during the cardiac refractory period. This data is presented in a graphical format for interpretation by a trained physician. The MI-1000 is also used for the measurement of SAECG indices. The MI-1000 should be used only as an adjunct to clinical history and the results of other noninvasive and/or invasive tests.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Per Zuckerman

(Division Sign-Off) 4/3/09
Division of Cardiovascular Devices

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